

### REMARKS

Applicant has reviewed and considered the Office Action dated June 7, 2007 and the cited reference therein. In response thereto, Claims 29 and 34 have been amended and new Claim 38 has been added. No new matter has been added by these amendments. In view of the amendments and the following remarks, Applicant requests reconsideration and allowance of the pending claims.

#### Summary of Telephone Interview of September 6, 2007

The Examiner held a telephone interview with Nathan Witzany, a representative for Applicant, on September 6, 2007. During the telephone interview, the independent claims were discussed. The Examiner indicated that Zdeblick (U.S. Patent No. 5,984,967) does not disclose complete occlusion. The previously pending independent Claims 29 and 34 have been amended to overcome Zdeblick accordingly.

During the interview, the Examiner also asserted that Zdeblick discloses a lumen, in that the space between vertebrae, as illustrated in Figures 6, 7, and 13(a)-(d), is a lumen. Applicant respectfully, though strongly, asserts that the space between vertebrae is not a lumen, and therefore, Zdeblick does not disclose a lumen occlusion device as recited in Applicant's new Claim 38. Specifically, Zdeblick does not disclose a "plug being configured and dimensioned to occlude flow through the lumen." The Examiner asserts that the definition of lumen is broad enough to read on the space between vertebrae. However, Applicant directs the Examiner to paragraph [0027] of Applicant's specification, which recites:

As used herein, "lumen" is defined as the space or cavity in the interior of a tubular structure or organ, such as an artery, vein, tube or duct, such as the bile duct.

Section 2173.01 of the MPEP states:

A fundamental principle contained in 35 U.S.C. § 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially

in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification.

Section 2111.01(IV) reinforces the concept:

Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999).

Therefore, Claim 38 is patentably distinguishable over Zdeblick. If the Examiner maintains that Zdeblick discloses a lumen occlusion device, Applicant invites the Examiner to illustrate, in detail, the manner in which the space between vertebrae fits with this definition of lumen, i.e., “the space or cavity in the interior of a tubular structure or organ, such as an artery, vein, tube or duct, such as the bile duct,” supplied by Applicant.

Rejections Under 35 U.S.C. § 102

Claims 29-32 and 34-35 are rejected under 35 U.S.C. § 102(b) as being anticipated by Zdeblick (U.S. Patent No. 5,984,967). Applicant respectfully traverses the rejection for at least the following reasons.

Claim 29, as currently amended, is directed to a lumen occlusion device. The lumen occlusion device comprises, in part, a “plug being configured and dimensioned to substantially completely occlude flow through the lumen.”

Claim 34, as currently amended, is directed to a method of occluding a body lumen. The method comprises, in part, “providing a device comprising a plugging means adapted for substantially completely occluding flow through the body lumen.”

Zdeblick does not disclose “substantially completely” occluding flow through a body lumen. Rather, Zdeblick discloses an osteogenic fusion device for implantation into the intervertebral space left after the removal of a damaged spinal disc. Zdeblick, Col. 1, ll. 12-14. The fusion device comprises vascularization openings for providing a passageway for vascularization to occur between the implant material within the interior of the device and the surrounding tissue. Zdeblick, Col. 5, ll. 59-65. However, the fusion device disclosed in Zdeblick does not occlude the flow through a body lumen. Particularly, the fusion device

disclosed in Zdeblick does not disclose “substantially completely” occluding flow, and the Examiner, in the telephone interview on September 6, 2007 summarized above, indicated the same.

Therefore, Claims 29 and 34 are patentably distinguishable over Zdeblick. Claims 30-32 and 35 depend from, and incorporate all the limitations of, either Claim 29 or Claim 34. Thus, Claims 30-32 and 35 are also patentably distinguishable over Zdeblick. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 33 and 36-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zdeblick (U.S. Patent No. 5,984,967), as applied to Claims 29 and 34 above, and further in view of Wallace (U.S. Patent No. 6,585,754). Applicant respectfully traverses the rejection for at least the following reasons.

As stated previously, Zdeblick does not disclose “substantially completely” occluding flow through a body lumen. Furthermore, Zdeblick is not properly combinable with Wallace to modify the osteogenic fusion device of Zdeblick to “substantially completely” occlude flow through a body lumen. Zdeblick discloses an osteogenic fusion device for implantation into the intervertebral space left after the removal of a damaged spinal disc. Zdeblick, Col. 1, ll. 12-14. The fusion device comprises vascularization openings for providing a passageway for vascularization to occur between the implant material within the interior of the device and the surrounding tissue. Zdeblick, Col. 5, ll. 59-65.

Zdeblick does not, however, disclose a device that is suitable for lumen occlusion. The device disclosed in Zdeblick is a threaded device configured to be screw threaded into the end plates of adjacent vertebrae. Zdeblick, Col. 5, ll. 18-20. Furthermore, the device includes parallel truncated side walls that are preferably flat to facilitate insertion of the fusion device between the end plates of the adjacent vertebrae and provide an area between for bony fusion. Zdeblick, Col. 5, ll. 39-43. With truncated side walls, the device gives the appearance, at its end view, of an incomplete circle. Zdeblick, Col. 5, ll. 45-47. Because of these characteristics, the fusion device disclosed in Zdeblick is not conducive to lumen occlusion, particularly lumen

occlusion of a lumen as defined by Applicant as "the space or cavity in the interior of a tubular structure or organ, such as an artery, vein, tube or duct, such as the bile duct." Therefore, there is no reasonable expectation of success in modifying the device of Zdeblick with the teachings of Wallace.

Therefore, Claims 29 and 34 are not made obvious by Zdeblick in view of Wallace. Claims 33 and 36-37 depend from, and incorporate all the limitations of, either Claim 29 or Claim 34. Thus, Claims 33 and 36-37 are also not made obvious by Zdeblick in view of Wallace. Reconsideration and withdrawal of the rejection is respectfully requested.

**Conclusion**

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

This response is being submitted on or before September 7, 2007 making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

Respectfully submitted,

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